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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,196	04/26/2001	Ichiro Hirao	55729	6079
21874	7590	02/05/2004		
EDWARDS & ANGELL, LLP P.O. BOX 55874 BOSTON, MA 02205			EXAMINER HENRY, MICHAEL C	
			ART UNIT 1623	PAPER NUMBER

DATE MAILED: 02/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/787,196

Applicant(s)

HIRAO ET AL.

Examiner

Michael C. Henry

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Claims 1-12 are pending in application

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The information disclosure statement filed complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file and the information referred to therein has been considered as to the merits.

Claim Objections

Claim 9 is objected to because of the following informalities: The claim recites the phrase “introducing a group to be able to for additional hydrogen bonds” which appears to contain a typographical error. It appears that the word “for” should be replaced by the word “form”. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The specification, while being enabling for

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the introducing specific groups, like dialkylamino or thiophene, does not reasonably provide enablement for the introducing of groups (which implies all chemical groups) that can form or create steric hindrance. First, in claim 1, the applicant claims "A method for constructing selective base pair comprising introducing a group having ability to form steric hindrance between bases in nucleic acid base." The introducing of groups having the ability to form steric hindrance is not enabled, since there are numerous chemical groups that can be introduced in the several bases of nucleic acid, resulting the enormous permutations of base pairs of which the applicant is not enabled. Furthermore, there are several ways (which ~~is~~ depends on the specific base) in which the said group can be introduced. Therefore, the introducing of groups having the ability to form steric hindrance by one method is not enabled by the instant disclosure. Claims 4 are also not enabled for the introducing of groups having the ability to form steric hindrance because of the above stated reasons.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "constructing" in claims 1 and 4, is a relative term which renders the claims indefinite. This term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. More specifically, it is unclear what constitutes

constructing selective base pair or how the base pair is constructed. For example, it is unclear where and how applicant's claimed dialkylamino group is introduced or located in the absence of a specific base, since there are several location (e.g. atomic points of attachment) and ways to "introduce" a group on a base.

Claim 1 recites the phrase "introducing a group having the ability to form steric hindrance ". However, the claim is indefinite because it is unclear which groups has the ability to cause, form or create steric hindrance, especially between base pairs which have several site (atom bonding sites) at which the said "introduction" or substitutions can occur. Furthermore, in the absence of a chemical structure or core (such as a specific natural nucleic acid base), the point, location or position of attachment in which the group is introduced is unclear and indefinite. More specifically, this phrase is vague and indefinite and, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 9 recites the limitation "introducing a group to be able to for additional hydrogen bonds". However, the claim is indefinite because, it is unclear whether or not it is imperative that the group has to form additional hydrogen, since the group only has "to be able to form additional hydrogen bonds". More specifically, this term is vague and does not further limit the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1,3,4,5,11,12 are rejected under 35 U.S.C. 102(b) as being anticipated by Tor et al. (Journal of the American Chemical Society (1993), 115, 4461-4467).

In claim 1, applicants claim "A method for constructing selective base pair comprising introducing a group having ability to form steric hindrance between bases in nucleic acid base. Tor et al. disclose applicant's method for constructing selective base pair (5-methylisoC and N⁶-(6-aminohexyl)isoG) comprising introducing a group (an aminoheptyl group) having ability to form steric hindrance between bases in nucleic acid base (see page 4462, figure 3). In claim 4, applicant claims "a method for constructing selective base pair comprising introducing a group having ability to form steric hindrance and electrostatic repulsion and stacking action between bases in nucleic acid base. Tor et al. disclose applicant's method for constructing selective base pair comprising introducing a group having ability to form steric hindrance and electrostatic repulsion and stacking action between bases in nucleic acid base (see page 4462, figure 3). In claim 5, applicant claims "The method according to claim 4 wherein the group having ability to form steric hindrance and electrostatic repulsion, and stacking action is a group to hinder formation of base pair with base part of natural nucleic acid." Tor et al. disclose applicant's method for constructing selective base pair comprising introducing a group having ability to form steric hindrance and electrostatic repulsion and stacking action between bases in nucleic acid base (see page 4462, figure 3). In claim 11, applicant claims "The method according to any of claims 1 - 10 wherein the base pair is a base pair which can be recognized by polymerase. Tor et al. disclose applicant's method according to any of claims 1 wherein the base pair is a base pair which can be recognized by RNA polymerase (see page 4462, figure 3, and the paragraph

above Results and discussion). Claim 12 which is a limitation of claim 11, wherein the polymerase is DNA polymerase or RNA polymerase, is also anticipated by Tor et al. (see page 4462, figure 3, and the paragraph above Results and discussion).

Claims 1,2, 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Gundersen (Tetrahedron Letters (1994), 35(19), 3155-8).

In claim 1, applicants claim "A method for constructing selective base pair comprising introducing a group having ability to form steric hindrance between bases in nucleic acid base. Gundersen discloses applicant's "A method for constructing selective base pair comprising introducing a group having ability to form steric hindrance between bases in nucleic acid base (see abstract). In claim 2 applicant claims "The method according to claim 1 wherein the group having ability to form steric hindrance is a group to hinder formation of base pair with base part of natural nucleic acid." Gundersen discloses applicant's method of claim 2 according to claim 1 wherein the group having ability to form steric hindrance is a group to hinder formation of base pair with base part of natural nucleic acid. (see abstract). It should be noted that Gundersen 's base is the same as applicants base, therefore Gundersen's base should possess same functional properties or abilities as applicant's base. In addition, because applicant's method for constructing selective base pair comprises only, the introducing a group into the nucleic acid base, Gundersen also introduced a same group (the aromatic heterocyclic group, thiophene group) into the their base to produce the same base. In other words, there is no other limitation in the method that indicates a difference. Claims 4-8, which are drawn to specific abilities or functions of the said group, are also encompassed by this rejection.

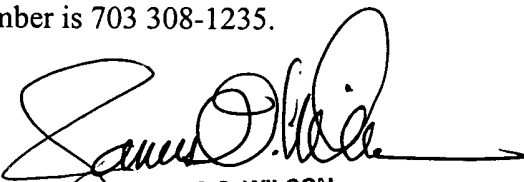
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 703 308-7307. The examiner can normally be reached on 8:30 am to 5:00 pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703 308-4624. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1235.

MCH

January 22, 2004.



JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
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